IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SHAYONNA FEATHERSTONE et al.	:	
	:	
v.	:	Civil No. WMN-07-1120
	:	
KENNEDY KRIEGER INSTITUTE INC. et al.	:	

MEMORANDUM

Before the Court is Plaintiffs' motion to remand this action to the Circuit Court for Baltimore City, Maryland, Paper No. 33, and Defendants' Motion to Dismiss for Failure to Join a Rule 19 Party, or In The Alternative, Motion to Join the NIEHS.[1] Paper No. 22. The motions have been fully briefed and are now ripe for

[1]Defendants' motion to dismiss or to require joinder of the NIEHS, which raises essentially identical arguments as were raised in opposition to the motion to remand, will be denied because Defendants fail to demonstrate that NIEHS is an "indispensable" party to this action. See Fed. R. Civ. P. 19(b) (stating that, if joinder is not feasible, the Court "shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable"); See also 7 Charles A. Wright, Arthur R. Miller & Mary K. Kane, Federal Practice and Procedure § 1617 (3d ed. 2001) (noting that "when relief can be granted to a party without affecting the United States, the government usually will not be held to be indispensable to the action"). Joinder is not feasible where sovereign immunity would bar suit and, in the instant case, pursuant to the Federal Tort Claims Act (FTCA), Plaintiffs would be barred by sovereign immunity from bringing suit against NIEHS as they did not exhaust administrative remedies, assuming the facts could even support a claim against NIEHS. See Def.'s Reply at 9 (arguing that the FTCA provides the means by which NIEHS could be sued and acknowledging the existence of "pre-requisites to filing suit" under the FTCA with which Plaintiffs have not complied); See also, e.g., Gould v. United States Dep't of Health and Human Servs., 905 F.2d 738, 741 (4th Cir. 1990) (government's waiver of sovereign immunity under the FTCA is limited and requires "presentation of a claim to the appropriate federal agency" prior to bringing suit).

review. Upon review of the pleadings and the applicable case law, the Court determines that no hearing is necessary and that the Plaintiffs' motion to remand will be granted and Defendants' motion to dismiss will be denied.[2]

I. FACTUAL AND PROCEDURAL BACKGROUND

This action arises out of Plaintiffs' participation in a non-therapeutic[3] research program known as the "Treatment of Lead-Exposed Children" (TLC), which was designed to "assess the effects of lead chelation with succimer[4] in children[.]" Treatment of Lead-Exposed Children Trial Protocol (Protocol) at §

[2]Also pending before this Court is Defendants' Motion for Leave to Respond to Plaintiffs' Request for Costs and Attorneys' Fees. Paper No. 42. Defendants assert that Plaintiffs raised this request for the first time in their Reply brief. Plaintiffs, in their opposition to the motion, withdrew any purportedly new request for attorney's fees, but maintained that they requested "costs" pursuant to 28 U.S.C. § 1447(c) in their Motion to Remand. Paper No. 43, ¶¶ 2, 4. To the extent Plaintiffs still seek costs, the Court denies their request and Defendants' motion is denied as moot.

[3]A therapeutic research study is one designed to "directly help or aid a patient who is suffering from a health condition[.]" Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 812 n.2 (Md. 2001). Non-therapeutic research, by contrast, "is not designed to directly benefit the subjects utilized in the research, but rather, is designed to achieve beneficial results for the public at large[.]" Id. Because succimer, the drug tested in the TLC Study, conferred no known, long-term benefit to children with blood lead levels in the range of the subjects, the study was classified as non-therapeutic.

[4]Succimer is a heavy metal chelating (binding) agent approved by the FDA for treatment of children with blood lead levels in excess of 45 micrograms per deciliter.

1.1.[5] The study was funded by the National Institute of Environmental Health Sciences (NIEHS)[6] in cooperation with the Office of Research on Minority Health (ORMH) at the National Institutes of Health (NIH) and the Center for Disease Control and Prevention (CDC). TLC was carried out at four Clinical Centers (CC) throughout the United States located in Baltimore, Philadelphia, Newark (New Jersey), and Columbus (Ohio). The only CC at issue in the instant case was located in Baltimore and was based at the Kennedy Krieger Institute (KKI), in association with Johns Hopkins University (JHU) and the University of Maryland. Defendants KKI and Cecilia Davoli, an employee of KKI and a co-investigator for TLC, removed this action from the Circuit Court for Baltimore City to this Court pursuant to the federal officer removal statute, 28 U.S.C. § 1442(a)(1), on the assertion that they were acting under the direction of a federal officer in administering the Baltimore portion of the TLC study.

On August 27, 1992, NIEHS began soliciting proposals for what would become TLC. It requested proposals "for the planning, conduct, analysis, and reporting of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-

---

[5]The study initially was known as the "Toxicity of Lead in Children Trial." See Toxicity of Lead in Children Trial – Clinical Center Contract.

[6]NIEHS is a subsidiary of the NIH. NIH is a branch of the United States Department of Health and Human Services (DHHS).

associated cognitive delay in young children." RFP at C.1. In response to the RFP, on November 24, 1992, KKI submitted a Technical Proposal to NIEHS. On June 29, 1993, NIEHS awarded a contract (the Contract) to KKI to operate one of the four CCs.

Under the Contract, NIEHS would provide funding for 5 years, with a total anticipated cost of $5,765,029.00. Contract at § B.2.a. The five-year period of funding consisted of three phases: 1) 9-12 months for planning; 2) 1 year for enrollment and treatment; and 3) 3 years of follow-up. The precise "protocol and strategies" for the trial were to be developed during the planning phase by a Steering Committee consisting of the Principal Investigator(PI) from each CC, the PI of the Coordinating Center, and the NIEHS Project Officer. Id. at § C.2.

Children generally were referred for participation in TLC by their treating physicians. In order to be eligible to participate in TLC, a child had to reside in a pre-designated area (catchment area) and have a confirmed pre-existing blood lead level in the range of 20-44 micrograms per deciliter. Protocol at § 3. Because succimer was not indicated for children who continued to be exposed to lead, a condition for enrollment in the study was that the child's residence was not "too lead-hazardous to be adequately cleaned." Id. Two home visits were conducted prior to a child being deemed eligible for TLC. Id. at

§§ 3.1-3.2.

Prior to assessing eligibility and again prior to enrollment in TLC, the consent of a parent or legal guardian was required. The Steering Committee drafted and approved the language for two informed consent forms (IC) for the two stages of consent. Each IC stated that "[a]ll children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint[.]" Id. at App. 2 ("Pre-Enrollment Informed Consent" and "Enrollment Informed Consent" forms).[7]

After enrollment in TLC and prior to randomization, a "TLC cleaning crew" returned to each child's residence to clean it. Id. at § 6.3. The clean-up measures set forth in the Protocol consisted of temporary removal of all furnishings, washing of painted ledges (window sills, etc.) with a detergent solution, vacuuming of most surfaces and rugs with HEPA-equipped vacuums, disposal of deteriorated rugs, and a minimal level of "paint stabilization"[8] as conditions required. Id. The Protocol made

---

[7]Both IC forms further stated that the child subjects would benefit from participation in TLC because personnel would "look carefully at [the child's] home for lead dust and chipped paint" and "clean-up the lead dust in [the child's] home." Protocol at App. 2.

[8]"Paint stabilization" as an "interim option" could be utilized where paint deterioration was localized and would consist of the removal of loose paint either with a damp towel or sponge or with a HEPA vacuum, followed by application of contact paper or a fresh coat of paint to the surface. Protocol at § 6.4. If deterioration was "extensive," "proper paint abatement" or relocation of the child was required for the child to be

clear, however, that TLC was not designed to "oversee comprehensive lead paint abatement," id., and the Contract specifically states that the contractor "shall not expend contract funds for lead abatement." Contract at § B.4.g.

Subsequent to clean-up activities and other preliminary testing of the child subjects, the treatment phase of TLC began. In the treatment phase, half of the children received one to three courses[9] of succimer chelation therapy, while the other half received a sugar-pill. Both treatment groups also received identical vitamin and mineral supplements. The children's blood-lead levels and cognitive functioning were then followed and tested to determine the efficacy of the drug for several years after treatment.

Plaintiffs are siblings who participated in the study as minor children. Shayonna Featherstone was born on October 22, 1992, and Keona Featherstone was born on September 11, 1993. From 1994 to 1997, Plaintiffs resided in two homes within the TLC catchment area.[10] Plaintiffs allege that Defendants KKI, JHU, and the Internal Review Board of the Johns Hopkins University

---

eligible to participate in TLC. Id.

[9] A course of succimer treatment consisted of 1050 mg/m per day for 7 days (in three doses), followed by 700 mg/m per day for 19 days (in two doses).

[10] It is unclear from the Complaint whether Shayonna and Keona moved midway through the study, whether they resided in separate residences throughout the study, or whether they alternated time at both residences described in the Complaint.

School of Medicine's Joint Committee on Clinical Investigation (IRB),[11] jointly facilitated the administration of the study. Individual Defendant Cecilia Davoli served as a co-investigator in the study. Defendant Helen Heath, individually and trading as "Lady H Enterprises," served as a subcontractor who performed interventions[12] on the study homes. Plaintiffs allege that KKI and Davoli coordinated with Defendants N.A.C.I. Corporation, Shenan Management, Inc., Marc Medin, Nancy Medin, Pythagoras Passas, and Anne Passas, landlords of lead-containing homes, to secure homes for the study which would be rented to tenants with minor children.[13] In exchange, KKI and Davoli assisted the landlords in applying for grants or forgivable loans to perform interventions.

On March 22, 2007, Plaintiffs brought the instant action in

---

[11] Individual Defendants Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, and Hayden G. Braine are each named as members of the IRB during the relevant period, along with Defendant John/Jane Doe, representing any unknown members of the IRB.

[12] Plaintiffs use the term "intervention" to refer to activities designed to removed lead dust and lead hazards from the homes. Defendants use the terms "clean" or "clean up."

[13] Plaintiffs allege that, "in order to facilitate recruitment," Defendants offered the parents of the participants, "cash, gift certificates, and other financial rewards for allowing their children to remain in the study." Compl. ¶ 14. Defendants also allegedly promised that they would "look carefully at the children['s] homes to identify lead hazards," that "if their house did not 'qualify'" for the study, the child would be relocated to lead-safe housing, and that they would "clean up the lead" in the homes of children enrolled in the study. Id. ¶¶ 10-12.

the Circuit Court for Baltimore City, Maryland. In their Complaint, Plaintiffs allege eight counts: negligence (Counts I, IV, V and VI), negligent misrepresentation (Counts II, III), civil conspiracy (Count VII), and breach of fiduciary duty (Count VIII). Compl. ¶¶ 36-89. Plaintiffs allege, inter alia, that succimer was "not indicated for prophylaxis of lead poisoning in an environment containing lead hazards," that the parents of the children were not informed of this fact, that Defendants knew or should have known that the interventions performed on the study homes were "not sufficient to remove lead-based paint hazards," and that Plaintiffs received no benefit from participation in TLC, but were in fact harmed by it. Id. at ¶¶ 6-25.

Defendants KKI and Davoli removed this action on the assertion that, as persons acting under an officer of the United States, they are entitled to removal pursuant to 28 U.S.C. § 1442(a)(1).[14] Thereafter, Defendants moved to dismiss the Complaint for failure to join a necessary party or, in the alternative, for joinder of the NIEHS. Plaintiffs opposed the motion, arguing that the NIEHS was neither necessary or indispensable under Rule 19 of the Federal Rules of Civil Procedure in that the challenged aspects of TLC were within the

[14] While JHU and the IRB did not join in KKI and Davoli's Notice of Removal, JHU and the IRB did join in the opposition to Plaintiff's Motion To Remand and raise an independent justification for removal, which will be discussed, infra.

control of the Defendants, not NIEHS. Advancing similar arguments, Plaintiffs moved to remand.

II. STANDARD OF LAW

The federal officer removal statute, 28 U.S.C. § 1442(a)(1), provides that a state court action may be removed by "the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, sued in an official or individual capacity for any act under color of such office[.]" The Supreme Court has explained the purpose of Section 1442(a)(1) as follows:

> [T]he Federal Government can only act through its officers and agents, and they must act within the States. If, when thus acting, and within the scope of their authority, those officers can be arrested and brought to trial in a State court, for an alleged offense against the law of the State, yet warranted by the Federal authority they possess, and if the general government is powerless to interfere at once for their protection, - if their protection must be left to the action of the State court, - the operations of the general government may at any time be arrested at the will of one of its members.

Mesa v. California, 489 U.S. 121, 126 (1989) (internal quotations omitted).

Section 1442 creates an exception to the well-pleaded complaint rule "because it operates on the basis of issues generally thought to be defensive in character rather than on the content of the plaintiff's claims." 14C Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure § 3727 (3d ed. 1998). A defendant seeking removal bears the burden of demonstrating jurisdiction and, generally,

due to federalism concerns, removal statutes are strictly construed and all doubts will be resolved against removal. Md. Stadium Auth. v. Ellerbe Becket Inc., 407 F.3d 255, 260 (4th Cir. 2005). Courts have interpreted the federal officer removal statute broadly when addressing the immunity of individual federal officials, and more narrowly in cases involving government contractors. See Freiberg v. Swinerton & Walberg Prop. Servs., Inc., 245 F. Supp. 2d 1144, 1152 n.6 (D. Colo. 2002). For a government contractor to establish removal jurisdiction under this provision, it must "(1) demonstrate that it acted under the direction of a federal officer, (2) raise a federal defense to plaintiffs' claims and (3) demonstrate a causal nexus between plaintiffs' claims and acts it performed under color of federal office." Pack v. AC & S, Inc., 838 F. Supp. 1099, 1101 (D. Md. 1993) (citing Mesa, 489 U.S. at 124-25, 129-31, 134-35).

III. DISCUSSION

A. The R&M Study

This Court recently granted motions for remand in two actions concerning the "Lead-Paint Abatement Repair and Maintenance Study" (R&M), a study funded by the Environmental Protection Agency (EPA) to assess the effects of different levels of residential lead-paint abatement on the blood-lead levels of children residing in the homes. Wallace v. Kennedy Krieger Institute, Inc. et al., No. 07-1140 (D. Md. Aug. 14, 2007); Covington v. Kennedy Krieger Institute, Inc. et al., No. 07-1761

(D. Md. Oct. 12, 2007). Wallace and Covington involved many of the same Defendants as the instant action, including KKI, JHU, and the IRB.

Plaintiffs argue that the TLC and R&M studies are virtually identical and urge the Court to remand the instant action for the same reasons stated in Wallace.[15] See Mot. at 10-15 (discussing the similarities between TLC and R&M). Defendants respond that TLC and R&M are independent studies, that there are "clear differences between the studies" which warrant a "fresh evaluation of federal jurisdiction," and that "prior rulings by this Court regarding the R&M Study are not relevant to the analysis of the TLC Study and should not be considered." Opp'n at 10.

The Court agrees with Defendants that there are significant differences between TLC and R&M, but disagrees that the R&M study and the prior rulings of this Court are irrelevant to the instant case. The Court will consider the relevant similarities and differences in analyzing the issue of federal jurisdiction over the instant action.

B. Person acting under a federal officer

Defendants KKI and Davoli admittedly are not officers of the United States. Thus, to remove this action under § 1442(a)(1),

[15]As Covington was remanded after briefing in this matter was complete, Plaintiff relies only on the Court's ruling in Wallace. In any event, Covington and Wallace present essentially identical factual scenarios.

they must initially establish that they were "persons[16] acting under the direction of a federal officer." Wright, Miller & Cooper, supra, § 3727. To make this showing, Defendants must demonstrate that they were 1) acting under the direction of a federal officer and 2) that there is a causal nexus between Plaintiffs' claims and those acts performed under color of federal office. As one court has noted, these two elements tend to "converge into a single inquiry: whether the defendants are being sued 'based upon actions taken pursuant to federal direction.'" Ryan v. Dow Chem. Co., 781 F. Supp. 934, 945 (E.D.N.Y. 1992)(quoting Gulati v. Zuckerman, 723 F. Supp. 353, 358 (E.D. Pa. 1989)).

Plaintiffs' Complaint alleges injury resulting from KKI and Davoli's negligent management of the "partial lead-abatement interventions" and their alleged misrepresentations and omissions with respect to lead levels in the Plaintiffs' dwellings and the potential harm resulting from exposure to that lead. See, e.g., Compl. ¶¶ 36-41 (alleging that the interventions performed on Plaintiffs' homes violated the Baltimore City Housing Code). Plaintiffs' further allege that, by virtue of the IC forms, KKI and Davoli assumed certain duties towards the Plaintiffs which they subsequently breached. See id. ¶¶ 60-65 (alleging, inter alia, duties to ensure that a doctor monitored Plaintiffs' blood-

[16]It is clear that private corporations may be characterized as "persons" under Section 1442(a)(1). See Pack, 838 F. Supp. at 1103.

lead levels and "promptly and accurately report those test results" to Plaintiffs' family and to provide "ongoing medical care of the Plaintiffs' lead-paint poisoning and lead toxicity").

Plaintiffs contend that KKI and Davoli have failed to demonstrate that they were acting under the direct and detailed control of a federal officer with regard to the alleged acts. As this Court explained in Wallace:

> To demonstrate action under the direction of a federal officer for the purposes of § 1442(a)(1), a defendant must show that "the acts forming the basis of the state suit were performed pursuant to an officer's 'direct orders or comprehensive and detailed regulations.'" Freiberg, 245 F. Supp. 2d at 1149-50 (quoting Ryan[, 781 F. Supp. at 947]). Courts have held that this showing requires a defendant to demonstrate action under the direct control of an officer of the federal government, as opposed to the general control of an governmental agency. See, e.g., Good v. Armstrong World Indus., Inc., 914 F. Supp 1125, 1129 (E.D. Pa. 1996) (holding that "[a]cting under the direction of the Navy . . . is not the same as acting under the direct and detailed control of a federal officer"); see also Ryan, 781 F. Supp. at 947 (noting that proof that "relevant acts occurred under the general auspices of a federal office or officer" or that "a corporation participates in a regulated industry" is insufficient).

Slip. op. at 7-8.

KKI and Davoli contend that the Notice of Removal expressly alleges action under the direction of a federal officer, to wit, Dr. Walter J. Rogan, the NIEHS Project Officer (PO) for the TLC Study. Opp'n, ¶ 3. While the Notice of Removal filed by KKI and Davoli contains numerous allegations of general control exercised

by the NIEHS, the CDC[17], the Food and Drug Administration (FDA)[18], the DHHS, and the United States Congress, see, e.g., Notice of Removal ¶¶ 8-12, 25-29 (stating that "the federal government directed and controlled" KKI's actions and that "NIEHS maintained detailed, hands-on control over all phases" of the study), it also alleges direct control by Dr. Rogan. Specifically, KKI and Davoli assert that Dr. Rogan was appointed PO after the Contract was awarded to KKI; that, as PO, he was responsible for maintaining "complete surveillance of the technical performance" of the contract to ensure that contractors complied with the "specifications/requirements of the contract terms"; that Dr. Rogan was a member of the Steering Committee that developed the TLC Protocol; that "[f]inal authority over each and every aspect of this study rested with the NIEHS Project Officer"; and that Dr. Rogan performed site visits at KKI and visited residences involved in the study. Id. at ¶¶ 13, 15-16, 19-20.

In Wallace, this Court found the Notice of Removal deficient on its face because the defendants made "general reference to multiple agency employees" and alleged generally that the federal government controlled and directed the R&M study. See Wallace, slip op. at 8. In the instant case, KKI and Davoli, while making certain allegations of general control, clearly single out Dr. Rogan as the key federal officer responsible for administering

[17]The CDC performed the laboratory analysis of blood lead samples for study participants.

[18]The FDA approved NIEHS's "Investigational New Drug" application for use of succimer in the study.

TLC.[19]

The Court's inquiry does not end there, however, because under Section 1442(a)(1), Defendants cannot merely allege control on the face of the Notice of Removal, but must make a showing of actual control. See Good, 914 F. Supp. at 1129 (noting that a defendant has the burden to "set forth evidence showing that it did, in fact, act under a federal officer"). The Court begins with the affidavits signed by Davoli and Merrill Brophy, KKI's Project Manager for TLC. The affidavits detail the role of the Steering Committee, Dr. Rogan, NIEHS, the CDC, and the FDA in controlling aspects of the study. With regard to Dr. Rogan, both Davoli and Brophy aver that the Steering Committee "was charged with responsibility for virtually all aspects of the study," that "each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation," and that "[n]o decision was final without review by Dr. Rogan and the NIEHS." Aff. of Merrill Brophy ¶¶ 4-5; Aff. of Cecilia Davoli ¶¶ 4-5. With regard to the IC forms, Davoli avers that "the NIEHS directly controlled and approved the information provided to the Study participants and their families

[19]Defendants also suggest that NIEHS's contracting officer, Thomas Hardee, exercised direct and detailed control over TLC as the "sole agent of NIEHS" for purposes of the study and the only person who could approve funding changes. Opp'n at 5. The Notice of Removal, however, makes only one reference to "NIEHS's contracting officer" with respect to Mr. Hardee's role in approving the Contract after it was signed. Notice of Removal at ¶ 12. The affidavits attached to the Notice of Removal make no mention of Mr. Hardee, either by name or by title. The Court concludes that the Notice of Removal fails to allege any direct and detailed control by Mr. Hardee.

as well as the information contained in the Informed Consent forms" and that the IC form was approved by both the local IRB and the NIEHS IRB before it was used in TLC. Aff. of Cecilia Davoli ¶¶ 6, 12. Thus, Defendants argue that Dr. Rogan's position on the Steering Committee was such that he "specifically directed each and every facet of the TLC study[.]" Opp'n at 11.

The Court's review of the Contract and the Protocol, however, reveals that Dr. Rogan's role on the Steering Committee was more circumscribed. The "Administration" section of the Protocol states that "[c]entral policy for the Trial will be set by a Steering Committee[.]" Protocol at § 2.2; See also Contract at § C.2 ("The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase."). The Steering Committee was composed of seven members: one representative from each of the four CCs, a representative from the Harvard School of Public Health (serving as the Data Coordinating Center), a representative of the CDC, and the NIEHS PO (Dr. Rogan). Protocol at § 2.2. Dr. Rogan served ex officio and only voted to "resolve ties." Id. Thus, to the extent that the six "regular"[20] members agreed, Dr. Rogan did not have a vote on the Steering Committee.

The Court notes that, even to the extent that Dr. Rogan actively guided the decision making process through the Steering Committee as Brophy and Davoli aver, participation in a collaborative process with a federal officer is not the same as

[20]This is the term used in the Protocol.

acting "pursuant to an officer's 'direct orders or comprehensive and detailed regulations" as is required under Section 1442(a)(1). See Pack, 838 F. Supp. at 1103 (finding direct and detailed control where the government "specif[ied] and approve[d] the type of asbestos cloth to be used" by defendant in building turbine generators); McMahon v. Presidential Airways, Inc., 410 F. Supp. 2d 1189, 1197 (M.D. Fla. 2006)(finding direct and detailed control over a company contracting with the Department of Defense to provide air transportation and operational support services in Afghanistan where the government controlled crew qualifications and equipment and determined flight routes); See also Ryan, 781 F. Supp. at 947-49 (collecting cases). Thus, to the extent that Defendants rely on Dr. Rogan's role on the Steering Committee in support of federal jurisdiction, the Court concludes it has not met its burden of showing "direct and detailed control."

Even were this Court to have found that Dr. Rogan's role on the Steering Committee amounted to direct and detailed control, the lack of a causal nexus between that control and the acts alleged by Plaintiffs also would support remand. The Court initially notes, as KKI and Davoli concede, that a local entity, the Maryland Department of Housing and Community Development (DHCD), not the federal government, funded the "interventions" performed on study homes. See Opp'n at 24 (acknowledging that the "lead dust clean-up" efforts were to be performed "[p]ursuant to an unfunded mandate" in the Contract). Defendants contend,

however, that the funding source is irrelevant given that the study homes were "cleaned . . . in accordance with the strict requirements set forth in the Contract with NIEHS and the Trial Protocol approved by Dr. Rogan." Id. at 23-24.

The "Statement of Work" in the Contract specifically directed that KKI was to "evaluate children's homes" and "provide clean-up according to trial protocol." Contract at § C.2. The Protocol provides precise specifications as to how TLC personnel were to perform the environmental "clean-up" required by the Contract. See, e.g., Protocol at § 6.3 (stating that, "[i]f there is no carpeting on the floor, the floor will be vacuumed at the rate of one minute per square yard" and that floors will be washed using a "two bucket system"). In this respect, the instant case differs from the R&M study addressed by the Court in Wallace and Covington. See Wallace, slip op. at 10-11 (noting that the R&M Contract explicitly excluded the residential lead paint abatement from its scope).

Both the Contract and the Protocol provide a caveat, however, to any centralized policy with regard to clean-up efforts. The "Statement of Work" states that, while central policy for the "clean-up activities" will be developed by a subcommittee of the Steering Committee, "the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO." Contract at § C.2. Further, the Contract states that, "[i]f clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate

plans for working with them. Each Clinical Center shall be responsible for preparing its own clean-up efforts, in consultation with the Clean-up Subcommittee." Id.

Similarly, while the Protocol "establishes standards of environmental assessment and intervention" for the Clinical Centers, it represents a floor, not a ceiling, with regard to abatement efforts:

> Each Center will meet or exceed applicable local, state, and federal guidelines for the management of children with lead toxicity. See Appendix 3 for copies of the relevant laws, regulations, and guidelines. As resources permit, individual Centers may elect to provide environmental management beyond the common core. TLC efforts are not meant to substitute for lead paint abatement that would be required or encouraged by local health departments. See Appendix 4 for supplemental environmental protocols from the TLC Clinical Centers.

Protocol at § 6.1. In Appendix 4 of the Protocol, entitled "Supplemental Environmental Protocols," each Clinical Center set forth additional measures to be undertaken in its catchment area. The Baltimore protocol is revealing:

> [KKI] is negotiating with the State of Maryland Department of Housing and Community Development (DHCD) for funds to perform supplemental environmental interventions in the houses of children enrolled in the TLC trial. Those funds would enable enrollment of children living in a wider spectrum of housing conditions and would likely increase the effectiveness of the environmental protocols . . . . The primary supplemental protocol described below is referred to as the Repair and Maintenance (R&M) Level II protocol. Also described below is the R&M Level I protocol for houses requiring less intensive R&M work. [KKI] has experience with both R&M protocols as part of ongoing studies of interventions to reduce exposure to lead in residential paint and dust.

Id. at App. 4 (emphasis added); See also Pl's Reply, Ex. 6

(Letter from Mark Farfel at KKI to the Secretary of the DHCD stating that "NIEHS will not provide funds for lead remediation . . . beyond a professional cleanup" and that KKI "anticipate[s] that many children otherwise eligible [for TLC] will be disqualified because their houses will require repair and maintenance in addition to cleanup in order to be made lead-safe") (emphasis added). Thus, contrary to Defendants' contentions, the houses were not cleaned according to the central Protocol, but rather, KKI implemented supplemental measures consistent with its efforts in the R&M study which were funded by the DHCD and which exceeded the steps called for in the Contract and Protocol.

Moreover, as discussed, supra, the Protocol was not the product of detailed federal direction and control because it was developed by the Steering Committee, not by Dr. Rogan and was the product of collaboration with representatives from KKI and the other CCs. Thus, even to the extent that houses were cleaned in compliance with the central Protocol, for the same reasons that the Court found a lack of "direct and detailed control," there is an insufficient causal nexus between the acts complained of and acts performed under "color of federal office."

Similarly, with respect to the negligent misrepresentations[21] and failure to obtain truly informed consent

[21]Some of the negligent misrepresentations alleged by Plaintiffs concern representations made "prior to the lease" of the properties to the Plaintiffs. See Compl. ¶¶ 42-45 (Count II). While it is not entirely clear from the Complaint, it appears that Plaintiffs allege that KKI, Davoli, JHU, and the IRB

alleged by Plaintiffs in their Complaint, the Court concludes that, for the same reason that performance of the interventions was not causally connected to acts performed under color of federal office, representations made to Plaintiffs regarding the condition of their homes and the repairs/clean-up to be performed necessarily lack a causal connection. This is so because it is apparent that Defendants utilized discretion in determining the level of intervention to perform in a given residence and whether to exceed the scope of the work under the Contract/Protocol as discussed above. As such, the representations made necessarily relied on anticipated acts that would be taken outside of any control by Dr. Rogan. For example, the Enrollment IC Form approved by the Steering Committee states: "All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint . . . ." Protocol at App. 2 (emphasis added). In contrast, the IC form signed by Plaintiff Keona Featherstone's mother stated: "All children in the TLC study will have their homes repaired and/or cleaned to get rid of lead dust and chipped paint . . . ." Mot., Ex. 14 (emphasis added).[22] Thus, the KKI

---

permitted the misrepresentations to be made by the landlords. Although Defendants contend that recruitment and enrollment was governed by the Contract and the Protocol, see Notice of Removal at 13, the Court's review of these documents finds no reference to any measures to encourage subjects to lease properties in order to find participants for TLC. See Contract at § C.2 (discussing recruitment).

[22]The IC Form attached to Plaintiffs' Motion to Remand is 6 pages long and is signed by Keona's mother and KKI personnel. The fifth page of the consent form, however, has a header indicating that it is from the "pre-enrollment" consent form, while the remainder of the pages are from the "enrollment"

IC form represented that homes could receive a greater level of abatement than that provided for in the Contract and Protocol. Accordingly, the Court concludes that Defendants have failed to satisfy their burden under Section 1442(a)(1) and that remand is appropriate.[23]

The Court notes that consideration of the purposes of Section 1442(a)(1) supports this result. As the Freiberg Court opined, "[b]ecause [Section 1442(a)(1)] is premised on the protection of federal activity and an anachronistic mistrust of state courts' ability to protect and enforce federal interests and immunities from suit, private actors seeking to benefit from its provisions bear a special burden of establishing the official nature of their activities." 245 F. Supp. 2d at 1150 (emphasis in original). The instant case involves a research trial of a lead chelating agent. The Plaintiffs' allegations primarily concern the abatement of lead in the homes of the children in the study and representations made to the Plaintiffs' concerning the condition and safety of their homes. The only federal interest asserted by Defendants in its Notice of Removal is the interest in "uniformity of interpretation and application of federal laws

---

consent form. The two forms are largely the same as approved by the Steering Committee, but there are some differences. It is unclear whether this page was accidently included at the time that the form was signed or whether this page was mistakenly included in the attachment by Plaintiffs.

[23]Given that Defendants failed to make the requisite showing under the first and third prongs of the Section 1442(a)(1) test, the Court need not address the second prong, whether Defendants raise a colorable claim to a federal defense.

governing scientific research involving children." See Notice of Removal ¶ 27.

In the Court's view, NIEHS's exercise of control over aspects of the study was designed in large part to ensure the relative uniformity of procedures in a multi-center research trial in order to promote the validity of the results of the study, not to further any federal policy. To this end, NIEHS required a central Protocol, but excepted certain aspects of the study from that Protocol if variations would not impact the validity of the results. See, e.g., Amendment to the RFP, p. 7 (noting that "[t]here is nothing in the RFP that says that children should not have their sources of lead abated, and the trial comparison is unaffected by abatement if treatment and placebo children have their sources abated similarly."). In many ways, the interests at stake were uniquely local - finding solutions to the dangerous conditions of the low-income housing stock in Baltimore and the treatment of children in Baltimore who had been exposed to lead paint. This is not a case where federal policy is thwarted by allowing adjudication in a state forum.

Finally, without deciding whether, under the second prong of the federal officer removal test, Defendants have in fact raised a colorable federal defense, several courts have questioned whether the defense asserted by the Defendants - the government contractor defense[24] - is of the type that should support removal

[24]The government contractor defense is based in federal common law and requires a showing that: "(1) the United States approved reasonably precise specifications; (2) the equipment

under Section 1442(a)(1). See Freiberg, 245 F. Supp. 2d at 1151 n.5 (noting that it is questionable whether the government contractor defense "is the type of federal interest or immunity for which § 1442(a)(1) was intended to provide an exclusively federal forum"); Good, 914 F. Supp. at 1131 (stating that the government contractor defense is "not subject to [state court] manipulation" in the way that a federal officer's defense of official immunity might); Ryan, 781 F. Supp. at 951 (opining that the government contractor defense "raises straightforward common law tort issues that the state courts are as adept at handling as the federal judiciary").

C. Removal Under Section 1441

Lastly, Defendants IRB and JHU raise for the first time in Defendants' opposition to the Motion to Remand the argument that this Court has original jurisdiction over this action because certain of Plaintiffs' claims arise under federal law. See Opp'n at 29-32. This identical argument was raised in Wallace based on the same federal regulations cited by Plaintiffs in their

---

conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." Boyle v. United Techs. Corp., 487 U.S. 500, 512 (1988). Originally thought to be applicable only to military procurement contracts, several courts have since applied the defense to civilian contracts and to service contracts entered into by the government. See, e.g., Bowers v. J&M Discount Towing, LLC, 472 F. Supp. 2d. 1248 (D.N.M. 2006) (IRS contract with an auto towing company for the towing of vehicles to auction sites for satisfaction of tax liens).

Complaint.[25] Without deciding whether this argument may be raised for the first time at this stage in the removal proceedings,[26] the Court concludes, for the same reasons stated in Wallace, that because "the essential elements of Plaintiffs' state law claims may exist independent of the regulatory duties and because a violation of those duties do[es] not give rise to a private federal cause of action, removal based upon federal question jurisdiction [is] not appropriate. Wallace, slip op. at 11-14.

IV. CONCLUSION

For the above stated reasons, Plaintiffs' Motion to Remand will be granted. A separate order consistent with this memorandum will follow.

/s/
William M. Nickerson
Senior United States District Judge

Dated: November 6, 2007

[25]The regulations at issue can be found at 45 C.F.R. § 46.101 et seq. and 45 C.F.R. § 46.401, et seq. and are discussed in Wallace.

[26]As noted earlier, Defendants IRB and JHU did not join in Defendants KKI and Davoli's Notice of Removal. KKI and Davoli asserted federal jurisdiction only on the basis of Section 1442(a)(1) in the Notice of Removal. While KKI and Davoli did assert that the exercise of removal jurisdiction would "promote uniformity in the application and interpretation" of the federal regulations cited by Plaintiffs, they did not argue this as an independent basis for removal for federal question jurisdiction. See Notice of Removal ¶¶ 25-29.